



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,740	05/30/2006	Abilio Melquiades Laguna Granja	CLAIM.P003	7047
28752	7590	07/21/2010		
LACKENBACH SIEGEL, LLP LACKENBACH SIEGEL BUILDING 1 CHASE ROAD SCARSDALE, NY 10583			EXAMINER CLARK, AMY LYNN	
			ART UNIT 1655	PAPER NUMBER
			MAIL DATE 07/21/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/549,740

Applicant(s)

LAGUNA GRANJA ET AL.

Examiner

Amy L. Clark

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14, 15 and 26-32 is/are pending in the application.
- 4a) Of the above claim(s) 26-30 and 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 15 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/06/2010 has been entered.

Election/Restrictions

The election/restriction requirement remains for reasons of record.

Acknowledgment is made of the receipt and entry of the amendment filed on 04/06/2010 with the amendment of claims 14 and 15 and newly added claims 31 and 32.

Newly submitted claim 32 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The originally examined claims are drawn to a pharmaceutical composition obtained from Roystonea regia fruits comprising fatty acids. The newly added claim 32 is drawn to a pharmaceutical composition for treating BPH.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 32 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 14, 15 and 31 are under examination.

Claim Rejections - 35 USC § 102/103

Claims 14 and 15 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over El-Khalaty et al. (Applicants' IDS NPL Reference 4*).

El-Khalaty teaches an oil fraction obtained from *Oreodoxa regia* (royal palm) (which is synonymous with *Roystonea regia*) seeds (which reads on fruit, since the royal palm seed contains the fruit) comprising caprylic acid in an amount of 0.4%, capric acid in an amount of 0.4%, lauric acid in an amount of 11.1%, myristic acid in an amount of 5.5%, palmitic acid in an amount of 22.2%, palmitoleic acid in an amount of 9.8%, stearic acid in an amount of 3.0%, oleic acid in amount of 35.3%, linoleic acid in an amount of 17.3% and linolenic acid in amount of 3.5% (See table IV, page 273), which

read on the ranges of each fatty acid component of Applicants' pharmaceutical composition in claim 15. El-Khalaty further teaches that the oil is obtained through a process of first crushing the seed, then defatting the seed followed by subjecting the resulting seed meal to acidic and alkaline hydrolysis (See page 270).

Although El-Khalary does not expressly teach that the oil fraction is a pharmaceutical nor does El-Khalary teach that the composition comprises a mixture of esters of the fatty acids nor does El-Khalary teach that free fatty acids are enriched from ester hydrolysis, the claimed functional properties are inherent to the preparation taught by El-Khalary. The functional properties are inherent to the preparation taught by El-Khalary because the El-Khalary expressly teaches the same composition taught by Applicants based upon the fatty acid profile provided by El-Khalary and the method taught by El-Khalary of obtaining the fatty acid profile from the seeds of royal palm are one and the same as disclosed in the instantly claimed invention of Applicants. Thus, the oil fraction obtained from seeds of royal palm as taught by El-Khalary, a mixture of esters of the fatty acids, and free fatty acids enriched from ester hydrolysis are inherent to the oil fraction composition taught by El-Khalary. Therefore, the reference anticipates the claimed subject matter.

In the alternative, even if the oil fraction composition obtained from *Oreodoxa regia* (royal palm) (which is synonymous with *Roystonea regia*) seeds comprising caprylic acid in an amount of 0.4%, capric acid in an amount of 0.4%, lauric acid in an amount of 11.1%, myristic acid in an amount of 5.5%, palmitic acid in an amount of 22.2%, palmitoleic acid in an amount of 9.8%, stearic acid in an amount of 3.0%, oleic

acid in amount of 35.3%, linoleic acid in an amount of 17.3% and linolenic acid in amount of 3.5% taught by El-Khalary is not identical to the pharmaceutical composition claimed by Applicants with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the oil fraction composition taught by El-Khalary is likely to intrinsically possess the same characteristics (including with respect to the instantly claimed functional effects) of the pharmaceutical composition claimed particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed pharmaceutical composition obtained from the fruit of *Roystonea regia* would have been obvious to those of ordinary skill in the art within the meaning of USC 103. Accordingly, the claimed invention as a whole was at *least prima facie* obvious, if not anticipated by El-Khalary, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

With respect to the USC 102/103 rejection above, please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicant's claimed pharmaceutical composition is different from the oil fraction composition taught by El-Khalary and, if so, to what extent, from that of the discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Response to Arguments

Applicants' arguments concerning the 35 U.S.C. § 102(b)/103(a) rejection above have been thoroughly considered but are not deemed persuasive of error in the rejection.

Applicants argue that El-Khalaty et al. is directed to an extraction from the seeds only, which seed oil is intended to be used in a food product and that the present invention is directed to the whole fruit. Applicants further argue that the profile of fatty acids taught by El-Khalaty is different than that claimed by Applicants. However, this is not found persuasive because according to "Everyday mysteries: Fun Science Facts from the Library of Congress" (Reference V*), botanically speaking, a coconut is a fibrous one-seeded drupe, also known as a dry drupe, but that when using loose definitions, the coconut can be a fruit, a nut and a seed. "The Free Dictionary: palm" (Reference W) teaches that the seed size of the palm varies, as does the trunk height and diameter and the leaf length and that the fruits of palms, covered with a tough fleshy, fibrous, or leathery outer layer, usually contain a large amount of endosperm in the seed (stored food) (please note that "Everyday mysteries: Fun Science Facts from the Library of Congress" teaches Some scientists like to refer to the coconut as a water dispersal fruit and seed and that that in addition to the "baby" plant in the seed, there is the food to kick off its life called the endosperm. The endosperm is what makes up most of the seed and, in the coconut's case, is the yummy white stuff we eat, which reads on fruit). "The Free Dictionary: palm oil" teaches that palm oil is the fat pressed from the fibrous flesh of the fruit of many palms. Therefore, it is understood in the art that "seed" can be used interchangeably to mean the fruit of the palm. El-Khalaty also uses this

term loosely throughout the introduction, for example El-Khalaty teaches that "the characteristics and fatty acid composition of the *Oreodexa regia* (royal palm) oil from a lot of nuts from Cuba were studied by Stillman et al, and the constants of the oil were fat content (of the kernel)...the fatty acid composition of the oil was..." which demonstrates a difference between the seed as a whole (which contains the fruity pulp of the royal palm) and the kernel. El-Khalaty further teaches that seeds and kernels were investigated in the extraction of oil (See page 270). Finally, Stillman (Reference U*, prior art of record) teaches that the nut of the Cuban palm contains 25% oil and that upon further examination, the ripe fruit of the Cuban palm contains the same oil as that obtained from the kernel of the Cuban palm (again, demonstrating that "seed" contains fruit) and describes saponifying the oil and fractioning the oil to obtain a fatty acid profile. Therefore, it would be expected that at the very least the fatty acid profile of the fruit and of the seed (if there is indeed a difference) would be the same or similar between the oil obtained from the kernel and the fruit and the profile of the whole of the seed would be expected to be consistent with the profile of oil obtained from the fruit and the profile of the oil obtained from the kernel. Therefore, El-Khalaty reads at least on a mixture of primary fatty acids with 8 to 28 carbon atoms obtained from ripe fruit of *Roystonea regia* (synonymous with Cuban palm and Cuban palmiche), and at the very least anticipates the subject matter of claim 1, which does not recite exact amounts of each fatty acid and does not require that all of the fatty acids in the claim be present in the composition. Further, the method of obtaining the extract from El-Khalaty appears to be identical to the process, as claimed, by which Applicants have obtained their

extract of the Cuban palm fruit and would be expected to contain a similar profile.

Optimizing one particular fatty acid would have been obvious to one of ordinary skill in the art (as set forth above and in the previous Office Action).

As currently drafted, the claims remain rejected for the reasons of record and for the reasons set forth above.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571)272-1310. The examiner can normally be reached on Monday to Friday between 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amy L Clark/
Examiner, Art Unit 1655